

## **REMARKS**

### **I. Rejections or Objections to Claims in the Office Action**

The Office Action mailed March 9, 2005 rejects claims on the following bases:

- (1) Claims 1-4, 6, 8-18, 22 and 50-56 were rejected under 35 U.S.C. 102(b) as being anticipated by Vierra et al. 5,749,892;
- (2) Claim 5 was rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Furnish et al. 5,498,256;
- (3) Claim 7 was rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Garrison et al. 5,613,937;
- (4) Claims 19-21 were rejected under U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Hossain et al. 6,063,021;
- (5) Claims 23-26, 28, 30-35, 37, 39-50 and 57-68 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Bennetti et al. 5,894,843;
- (6) Claims 27 and 36 were rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Bennetti et al. 5,894,843 as applied to claims 23-26, 28, 30-35, 37, 39-50 and 57-68, further in view of Furnish 5,498,256; and
- (7) Claim 7 was rejected under 35 U.S.C. 103(a) as being unpatentable over Vierra et al. 5,749,892 in view of Bennetti et al. 5,894,843 as applied to claims 23-26, 28, 30-35, 37, 39-50 and 57-68, further in view of Garrison et al. 5,613,937.

Each of the foregoing rejections is responded to below, where each response references the number corresponding to each rejection set forth above.

## **II. Response to Rejections Made in the Office Action**

- (1) Claims 1-4, 6, 8-18, 22 and 50-56 are not anticipated under 35 U.S.C. 102(b) by Vierra 5,749,892.

The Office Action stated claims 1-4, 6, 8-18, 22 and 50-56 were anticipated by Vierra et al. 5,749,892. Vierra et al. discloses a medical device and a method of using the medical device to immobilize a portion of a stopped heart (see column 11, lines 65-66). The device includes a foot coupled to a shaft 3 at a pivot point 59 and to a rod 43 at a coupling point 49 separated from the pivot point. Axial movement of the rod via a mechanical actuator 69 with respect to the shaft rotates the foot about the pivot point. The actuator is configured to pivot the foot about the transverse axis (see column 4, lines 1-16). The foot comprises members 15 and 17 movable between an open configuration, where the arms are disposed apart in a “V” shape, and a collapsed configuration where the arms are disposed closer together in a substantially parallel configuration (see column 4, lines 23-32). The arms may be biased into the open configuration by a spring 41 (as shown in FIG. 3b), or an actuator (not shown) may be used for moving the arms between the open and collapsed configurations (see column 4, lines 32-35). In the open position, members 15 and 17 are preferably oriented at an angle between 15 and 50 degrees from each other and usually between 35 and 45 degrees (see column 7, lines 23-26). Members 15 and 17 each have a contact surface 27 for engaging tissue (see column 6, lines 58-66) and an inner surface 71 with a plurality of irrigation holes 73 (see column 8, lines 23-26). As shown in FIG. 2B, contact surface 27 and inner surface 71 of members 15 and 17 are 90 degrees relative to each other. Vierra et al. states that holes 73 are for delivering irrigation fluids to a surgical site or for suctioning fluids from a surgical site (see column 8, lines 22-38). Because holes 73 are for suctioning or delivery fluids to a surgical site, Vierra et al. fails to show or describe holes being positioned along a surface suitable for engaging tissue.

Vierra et al. only discloses members 15 and 17 as being movable relative to each other between two configurations, an open configuration and a closed configuration. Vierra et al. does not disclose any positions other than open and closed. In addition, Vierra et al. only discloses members 15 and 17 being parallel to each other in the closed configuration. In the open configuration, members 15 and 17 are disclosed as being oriented at an angle relative to each

other, as opposed to being oriented substantially parallel to each other. Therefore, members 15 and 17 are not disclosed as to move in a substantially parallel relationship relative to each other between an open configuration and a closed configuration.

The Office Action stated that Vierra et al. shows a device having an arm 43, and a mechanical actuator, knob 69, connected to one end of the arm, a spreader 51 connected to the other end of the arm and to the actuator. According to Vierra et al. members 15 and 17 are pivotally coupled to coupling member 19 (see col. 6, lines 59-61). Proximal ends 25 of members 15 and 17 are each rotatably coupled to tongue 31 of coupling member 19 by a pin 33 (see col. 7, lines 9-12). This configuration allows members 15 and 17 to pivot between an open position, where the members 15 and 17 are disposed apart in a general V-shape to a collapsed position, where the members 15 and 17 are together and generally parallel (see col. 7, lines 12-15). A torsion spring biases 41 biases members 15 and 17 into the open position. In the open position, members 15 and 17 will preferably be oriented at an angle between 15 and 50 degrees from each other (see col. 7, lines 22-25). Alternatively, an actuator mechanism (not shown) located at proximal end 7 of shaft 3 may be provided to allow the surgeon to selectively open and close members 15 and 17 (see col. 7, lines 44-47). Coupling member 19 has a coupling point 51 (see col. 7, lines 54-56). Coupling point 51 is not a spreader as described in the Office Action.

The Office Action stated that knob 69 incrementally spreads the members 15 and 17. According to Vierra et al. rotation of knob 69 slides rod 43 and link 45 in the distal direction thereby pivoting coupling member 19 and foot 11 about an axis transverse to the longitudinal axis of shaft 3 (see col. 8, lines 7-19). The Office Action stated that since knob 69 incrementally spreads the members 15 and 17, there are many positions between completely shut and completely open. However, Vierra et al. never discloses that knob 69 incrementally spreads the members 15 and 17. Vierra et al. only discloses that knob 69 incrementally pivots coupling member 19 and members 15 and 17 about an axis transverse to the longitudinal axis of shaft 3.

A rejection based on anticipation under 35 U.S.C. 102 requires all of the elements recited in the claims of the invention to be found within the four corners of the cited reference. Claim 1 calls for three positions whereas Vierra et al. only discloses a first configuration where the arms are parallel and a second configuration where the arms are in a substantially nonparallel V-shape configuration. No positions other than open and closed are disclosed by Vierra et al. Claims 1-4, 6, 8-18 and 51-53 include the limitation that the first and second tissue engaging members are

substantially parallel in the first position and at least one of the second and third positions. Thus the U.S.C. 102(b) rejection for claims 1-4, 6, 8-18 and 51-53 should be withdrawn.

Claims 22, 54-56 include the limitation that the first and second tissue engaging members are substantially parallel to each other in the first and second positions. This limitation is not disclosed in the Vierra et al. reference, thus the 35 U.S.C. 102(b) rejection for claims 22, 54-56 should be withdrawn.

Claim 50 includes the limitation of spreading the first tissue engaging member away from the second tissue engaging member while maintaining the first tissue engaging member substantially parallel to the second tissue engaging member a second distance after the first tissue engaging member has been coupled to the first tissue surface and second tissue engaging member has been coupled to the second tissue surface to place the substantially immobilized tissue under tension within a patient's body. This is not disclosed in Vierra et al., thus the 35 U.S.C. 102(b) rejection for claim 50 should be withdrawn.

(2) Claims 5 is not obvious under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Furnish et al. 5,498,256.

The Office Action stated claims 5 was rejected under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Furnish 5,498,256. Vierra et al. discloses a medical device and a method of using the medical device to immobilize a portion of a stopped heart (see column 11, lines 65-66). The device includes a foot coupled to a shaft 3 at a pivot point 59 and to a rod 43 at a coupling point 49 separated from the pivot point. Axial movement of the rod via a mechanical actuator 69 with respect to the shaft rotates the foot about the pivot point. The actuator 69 is configured to pivot the foot about the transverse axis (see column 4, lines 1-16). The foot comprises members 15 and 17 movable between an open configuration, where the arms are disposed apart in a "V" shape, and a collapsed configuration where the arms are disposed closer together in a substantially parallel configuration (see column 4, lines 23-32). The arms may be biased into the open configuration by a spring 41 (as shown in FIG. 3b), or an actuator (not shown) may be used for moving the arms between the open and collapsed configurations (see column 4, lines 32-35). In the open position, members 15 and 17 are preferably oriented at an angle between 15 and 50 degrees from each other and usually between 35 and 45 degrees (see column 7, lines 23-26).

Vierra et al. discloses members 15 and 17 as being movable relative to each other between two configurations, an open configuration and a closed configuration. Vierra et al. does not disclose a third position. In addition, Vierra et al. only discloses members 15 and 17 being parallel to each other in the closed configuration. In the open configuration, members 15 and 17 are disclosed as being preferably oriented at an angle relative to each other, as opposed to being oriented parallel to each other. Therefore, members 15 and 17 are not disclosed as to move in a parallel relationship to each other.

The Furnish et al. reference discloses a hand lever actuator for a forceps. The hand lever actuator includes an actuator rod coupled to an articulated member of a jaw configuration, wherein movement of the lever causes axial movement of the rod, thereby causing the articulated member of the jaw configuration to pivot between an open position and a closed position. In the open position, the articulated member of the jaw configuration is shown disposed apart in a "V" shape from the fixed member of the jaw configuration (see FIG. 1). Furnish et al. never discloses two members moving relative to each other in a parallel relationship. Further, the members are never disclosed being parallel to each other in an open configuration. In fact, in the open configuration, members 14 and 16 are disclosed as being oriented at an angle relative to each other, as opposed to being oriented parallel to each other.

The Office Action stated that it would have been obvious to modify Vierra et al. to use the actuator of Furnish, as it is merely the substitution of one known equivalent actuator for another. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Together the Vierra et al. reference and the Furnish et al. reference do not provide any motivation, suggestion or teaching for an actuator configured to operate a spreader to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position, wherein the first and second tissue engaging members are substantially parallel to each other in the first, second and third positions as required in claim 5.

Substitution of the Furnish hand lever for the Vierra et al. knob would yield a hand lever for controllably pivoting coupling member 19 and members 15 and 17 about an axis transverse to the longitudinal axis of shaft 3. The hand lever would have no control over the spreading of

members 15 and 17. Therefore, the rejection of claim 5 as being unpatentable over Vierra et al. 5,749,892 in view of Furnish et al. 5,498,256 should be withdrawn.

- (3) Claim 7 is not obvious under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Garrison et al. 5,613,937.

The Office Action rejected claims 7 under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Garrison et al. 5,613,937. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Together the Vierra et al. reference and the Garrison et al. reference do not provide any motivation, suggestion or teachings for an actuator configured to operate a spreader to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position, wherein the first and second tissue engaging members are substantially parallel to each other in the first, second and third positions as set forth in dependent claim 7. Substitution of the Garrison slide actuator for the Vierra et al. knob would yield a slide actuator for controllably pivoting coupling member 19 and members 15 and 17 about an axis transverse to the longitudinal axis of shaft 3. The slide actuator would have no control over the spreading of members 15 and 17. Therefore, the rejection of claim 7 as being unpatentable over Vierra et al. 5,749,892 in view of Garrison et al. 5,613,937 should be withdrawn.

- (4) Claims 19-21 are not obvious under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Hossain et al. 6,063,021.

The Office Action rejected claims 19-21 under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Hossain et al. 6,063,021. The Hossain et al. reference discloses a device having two members hinged together so that one member can rotate relative to the other member (see column 2, lines 1-7). The members are shaped to form a continuous closed loop having a central opening (see column 2, lines 11-15). The Hossain et al. reference teaches away from two members in parallel arrangement and, instead, claims a benefit for a continuous, closed loop, which can be removed readily after anastomosis of a graft (see column 1, lines 45-53).

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Together the Vierra et al. reference and the Hossain et al. reference do not provide any motivation, suggestion or teachings for an actuator configured to operate a spreader to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position, wherein the first and second tissue engaging members are substantially parallel to each other in the first, second and third positions as required in dependent claims 19-21. Therefore, the rejection of claims 19-21 as being unpatentable over Vierra et al. 5,749,892 in view of Hossain et al. 6,063,021 should be withdrawn.

(5) Claims 23-26, 28, 30-35, 37, 39-50 and 57-68 are not obvious under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Bennetti et al. 5,894,843.

The Office Action rejected claims 23-26, 28, 30-35, 37, 39-50 and 57-68 under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Bennetti et al. 5,894,843. Claims 23, 31 and 32 were amended without prejudice. The Office Action stated that the members 15 and 17 of Vierra are positioned incrementally using the rotational knob. However, as discussed above, Vierra et al. never discloses that knob 69 incrementally spreads members 15 and 17. Vierra et al. only discloses that knob 69 incrementally pivots coupling member 19 and members 15 and 17 about an axis transverse to the longitudinal axis of shaft 3.

Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Together the Vierra et al. reference and the Bennetti et al. reference do not provide any motivation, suggestion or teachings for an actuator configured to operate a spreader to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position, wherein the first and second tissue engaging members are substantially parallel to each other in the first, second and third positions as required in amended claim 23. Dependent claims 24-26, 28, 30 and 57-59 depend from claim 23 and include all the limitations of claim 23. Therefore, the rejection of claims 23-26, 28, 30 and 57-59 as being unpatentable over Vierra et al. 5,749,892 in view of Bennetti et al. 5,894,843 should be withdrawn. Together the Vierra et al. reference and the Bennetti et al. reference do not provide

any motivation, suggestion or teachings for an actuator configured to operate a spreader means to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position so a selective amount of spreading occurs as required in amended claim 31. Dependent claims 60-62 depend from claim 31 and include all the limitations of claim 31. Therefore, the rejection of claims 31 and 60-62 as being unpatentable over Vierra et al. 5,749,892 in view of Bennetti et al. 5,894,843 should be withdrawn. Together the Vierra et al. reference and the Bennetti et al. reference do not provide any motivation, suggestion or teachings for a method of immobilizing tissue which includes remotely controlling the spreading of first and second tissue engaging members among a first position and a second position so a selective amount of substantially uniform parallel spreading occurs as required in amended claim 32. Dependent claims 63-65 depend from claim 32 and include all the limitations of claim 32. Therefore, the rejection of claims 32 and 63-65 as being unpatentable over Vierra et al. 5,749,892 in view of Bennetti et al. 5,894,843 should be withdrawn. Together the Vierra et al. reference and the Bennetti et al. reference do not provide any motivation, suggestion or teachings for a method of placing tissue under tension which includes introducing a first tissue engaging member carried on an arm distal end and a second tissue engaging member carried on the arm distal end into a patient's body with the first tissue engaging member and second tissue engaging member configured substantially together, spreading the first tissue engaging member away from the second tissue engaging member a first distance after the first tissue engaging member and second tissue engaging member are within the patient's body, coupling the first tissue engaging member to a first tissue surface and the second tissue engaging member to a second tissue surface to substantially immobilize a tissue area within the patient's body, spreading the first tissue engaging member away from the second tissue engaging member while maintaining the first tissue engaging member substantially parallel to the second tissue engaging member a second distance after the first tissue engaging member has been coupled to the first tissue surface and second tissue engaging member has been coupled to the second tissue surface to place the substantially immobilized tissue under tension within a patient's body and fastening the arm to a stationary object to substantially fix the first tissue engaging member and the second tissue engaging member in relation to the stationary object as required in claim 48. Dependent claims 49-50 and 66-68 depend from claim 48 and include all the limitations of claim

48. Therefore, the rejection of claims 48-50 and 66-68 as being unpatentable over Vierra et al. 5,749,892 in view of Bennett et al. 5,894,843 should be withdrawn.

- (6) Claims 27 and 36 are not obvious under 35 U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Bennett et al. 5,894,843 as applied to claims 23-26, 28, 30-35, 37, 39-50 and 57-68, further in view of Furnish 5,498,256.

The Office Action rejected claims 27 and 36 under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Bennett et al. 5,894,843 as applied to claims 23-26, 28, 30-35, 37, 39-50 and 57-68, further in view of Furnish 5,498,256. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Together the Vierra et al. reference, the Bennett et al. reference and the Furnish reference do not provide any motivation, suggestion or teachings for an actuator configured to operate a spreader to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position, wherein the first and second tissue engaging members are substantially parallel to each other in the first, second and third positions as required in amended claim 23. Dependent claim 27 depends from claim 23 and include all the limitations of claim 23. Therefore, the rejection of claims 27 as being unpatentable over Vierra et al. 5,749,892 in view of Bennett et al. 5,894,843 and Furnish 5,498,256 should be withdrawn. Together the Vierra et al. reference and the Bennett et al. reference do not provide any motivation, suggestion or teachings for a method of immobilizing tissue which includes remotely controlling the spreading of first and second tissue engaging members among a first position and a second position so a selective amount of substantially uniform parallel spreading occurs as required in amended claim 32. Dependent claim 36 depends from claim 32 and include all the limitations of claim 32. Substitution of the Furnish hand lever actuator for the Vierra et al. knob would yield a hand lever actuator for controllably pivoting coupling member 19 and members 15 and 17 about an axis transverse to the longitudinal axis of shaft 3. The hand lever actuator would have no control over the spreading of members 15 and 17. Therefore, the rejection of claims 36 as being unpatentable over Vierra et al. 5,749,892 in view of Bennett et al. 5,894,843 and Furnish 5,498,256 should be withdrawn.

- (7) Claim 7 is not obvious under 35 U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Bennett et al. 5,894,843 as applied to claims 23-26, 28, 30-35, 37, 39-50 and 57-68, further in view of Garrison et al. 5,613,937.

The Office Action rejected claims 7 under U.S.C. 103(a) over Vierra et al. 5,749,892 in view of Bennett et al. 5,894,843 as applied to claims 23-26, 28, 30-35, 37, 39-50 and 57-68, further in view of Garrison et al. 5,613,937. Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching, suggestion or incentive supporting the combination. Together the Vierra et al. reference, the Bennett et al. reference and the Garrison et al. reference do not provide any motivation, suggestion or teachings for an actuator configured to operate a spreader to selectively control the movement of first and second tissue engaging members among a first position, a second position and a third position, wherein the first and second tissue engaging members are substantially parallel to each other in the first, second and third positions as set forth in dependent claim 7. Substitution of the Garrison slide actuator for the Vierra et al. knob would yield a slide actuator for controllably pivoting coupling member 19 and members 15 and 17 about an axis transverse to the longitudinal axis of shaft 3. The slide actuator would have no control over the spreading of members 15 and 17. Therefore, the rejection of claim 7 as being unpatentable over Vierra et al. 5,749,892 in view of Bennett et al. 5,894,843 and Garrison et al. 5,613,937 should be withdrawn.

Support for this amendment is clearly found in the application as originally filed. No new matter is presented.

The Office Action states that Vierra teaches using an actuator for providing a selective amount of spreading and that the actuator is knob 69. The applicants respectively disagree with the Office Action in that Vierra never discloses knob 69 as an actuator to selectively control the amount of spreading. In fact, according to Vierra et al. knob 69 controls the pivoting of coupling member 19 and foot 11 about an axis transverse to the longitudinal axis of shaft 3 (see col. 8, lines 7-19). The pivoting of coupling member 19 is an entirely different action than the spreading of members 15 and 17. The Office Action also stated that since knob 69 incrementally

spreads the members 15 and 17, there are many positions between completely shut and completely open. The applicants respectively disagree with the Office Action in that Vierra discloses that the foot comprises members 15 and 17 movable between an open configuration, where the members are disposed apart in a “V” shape, and a collapsed configuration where the members are disposed closer together in a substantially parallel configuration (see column 4, lines 23-32). The members may be biased into the open configuration by a spring 41 (as shown in FIG. 3b), or an actuator, which is not shown in any of the drawings, may be used for moving the members between the open and collapsed configurations (see column 4, lines 32-35). The only configurations disclosed by Vierra is an open configuration and a collapsed configuration. Vierra further discloses that in the open position, members 15 and 17 are preferably oriented at an angle between 15 and 50 degrees from each other and usually between 35 and 45 degrees (see column 7, lines 23-26). The applicants respectively disagree with the Office Action position that in the open configuration members 15 and 17 would be substantially parallel to each other.

Examination and reconsideration of the application as amended is requested. After amending and adding claims as set forth above, claims 1-68 are pending in the application and are now believed to be in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

A supplemental information disclosure statement accompanies this amendment. Please charge to Deposit Account No. 13-2546 the fee of \$180.00 which is required for the submission of the supplemental information disclosure statement.

A request for a two (2) month extension of time under 37 C.F.R. 1.136(a) has been filed with this amendment. Please charge to Deposit Account No. 13-2546 the fee of \$450.00 which is required for the two-month extension of time.

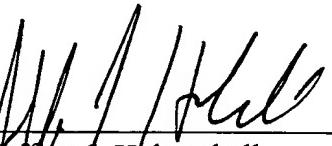
A Request for Continued Examination (RCE) under 37 C.F.R. 1.114 has been filed with this amendment. Please charge to Deposit Account No. 13-2546 the fee of \$790.00 which is required for the RCE.

If the Examiner comes to believe that a telephone conversation may be useful in addressing any remaining open issues in this case, the Examiner is urged to contact the undersigned attorney at 763-391-9661.

If any additional fee is required in connection with these papers, please charge such fee to Deposit account No. 13-2546.

Date July 21, 2005

By



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